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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,468	12/03/2001	Ernst Heinz	0093/00029	3433

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT PAPER NUMBER

1638

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/980,468	<b>Applicant(s)</b> HEINZ ET AL.	
	<b>Examiner</b> Elizabeth F. McElwain	<b>Art Unit</b> 1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 November 2004 and 04 February 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 8-14, 16-20 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) 2, 3 and 13, 14, 16-20, 22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5, 8-12 and 24-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The amendment filed February 4, 2005 has been entered.

The remarks filed November 8, 2004 have been entered.

Claims 6 and 7 are cancelled.

Claims 1-5, 8-14, 16-20 and 22-29 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restrictions***

This application contains claims 2, 3, 13, 14, 16-20, 22 and 23 drawn to an invention nonelected with traverse. In addition, claim 1 recites non-elected SEQ ID numbers. A complete reply to the final rejection must include cancellation of nonelected claims and non-elected SEQ ID numbers or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 2, 3, 13, 14, 16-20, 22 and 23 are withdrawn as drawn to non-elected inventions.

Claims 1, 4, 5, 8-12 and 24-29 are elected, to the extent they are drawn to SEQ ID NO: 1. Applicant is reminded of the requirement to cancel non-elected material and non-elected claims.

### ***Claim Rejections - 35 USC § 112***

1. Claims 1, 4-12 and 24-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
2. The rejection of the claims as indefinite in the recitation of delta-6-acetylenase and/or delta-6 desaturase activity is withdrawn in view of applicants' remarks.

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3. The rejection of the claims as indefinite in the recitation of part b), which is confusing as it seems to duplicate what is claimed in part c), which encompasses all sequences that code for SEQ ID NO: 2 is withdrawn in view of applicants' remarks.

4. Claim 1 and claims 4-12 and 24-29 dependent thereon are indefinite in the recitation of "negligible reduction in the enzymatic action", since it is unclear what would constitute a "negligible reduction", and the specification fails to define or clarify the use of this term.

Applicants' arguments filed November 8, 2004 have been fully considered but they are not persuasive. Applicants argue that this phrase is clearly defined on page 8 at lines 16-19 of the specification. The Examiner maintains that the definition in the specification asserts that "negligibly reduced" includes having as little as "at least 10%" of the activity of the initial enzyme. This is considered repugnant to the usual meaning of "negligibly reduced". This encompasses up to a 90% reduction in activity.

5. The rejection of claim 6, and claim 7 dependent thereon, is withdrawn in view of the cancellation of the claims

6. The rejection of claim 8 as indefinite in that they are unduly alternative in referring to "functional or nonfunctional" nucleic acid sequences is withdrawn in view of the amendment of the claim.

7. Claim 8 is indefinite in that it is unclear what is intended by "functional" since it is not stated what function is intended, and there is no antecedent basis for this phrase in claim 1.

Applicants' arguments filed November 8, 2004 have been fully considered but they are not persuasive. Applicants argue that this phrase is clearly defined in the specification. The

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Examiner maintains that the word “functional” is used in the specification, but that no definition of what would be considered “functional” with regard to the nucleic acid of the claims. The Examiner maintains that there is no antecedent basis for “functional” in claim 1. It is suggested that the word “functional” be deleted from the claim.

8. Claims 9 and 10, and claims 11 and 12 dependent thereon are indefinite in the recitation of “oil-producing organism”, since most, if not all, organisms produce some form of oil.

Applicants’ arguments filed November 8, 2004 have been fully considered but they are not persuasive. Applicants argue that this phrase is clearly defined in the specification. The Examiner maintains that the specification uses open language when referring to “oil-producing organisms”, listing several plant species. The specification does not set forth the metes and bounds of the claimed invention. While the claims are read in light of the specification, limitations set forth in the specification are not read into the claims.

Claim 26 is indefinite in that it seems to be missing words and does not make sense.

### ***Claim Rejections - 35 USC § 101***

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 24-29 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to an organism that encompasses a human.

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Claims 1, 4, 5, 8-12 and 24-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the last office action.

Applicants' arguments filed November 8, 2004 have been fully considered but they are not persuasive. Applicants assert that a representative number of compounds can meet the written description requirement and that the Examiner has not met his burden. Applicants also argue that the Examiner has not established undue experimentation. The Examiner maintains that she has met her burden in the statements set forth in the last office action and that applicants have not provided a representative number of compounds to define the genus claimed. The Examiner maintains that undue experimentation is not relevant to meeting the written description requirement.

10. Claims 1, 4, 5, 8-12 and 24-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as set forth in the last office action.

Applicants' arguments filed November 8, 2004 have been fully considered but they are not persuasive. Applicants assert that the specification provides enough guidance to practice the claimed invention, stating that methods for transforming organisms are provided and vectors are

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disclosed, and transformed plants are created in the examples. The Examiner maintains that the specification does not make clear what sequences are used in the examples. The Examiner maintains that the specification does not enable one skilled in the art to make and/or use the claimed invention for the reasons set forth in the last office action.

### ***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

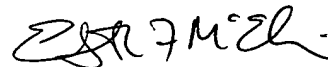
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Elizabeth F. McElwain, Ph.D.  
Primary Examiner  
Art Unit 1638

EFM